



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Roxarsone

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five new animal drug applications (NADAs) for roxarsone oral dosage form products at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following five NADAs for roxarsone oral dosage form products, used to make medicated drinking water for chickens, turkeys, and swine, because the products are no longer manufactured or marketed:

NADA	Proprietary Name
005-414	REN-O-SAL Tablets
006-019	Zuco Poultry Tablets

NADA	Proprietary Name
006-081	Korum Improved Formula
008-274	Pig Scour Tablets
093-025	3-NITRO Soluble

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 005-414, 006-019, 006-081, 008-274, and 093-025, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: December 20, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.